I. General Information

CAS Number:	C.I. Pigment Yellow 14 (CAS NO.: 5468757)
Name:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

II. Physical-Chemical Data

A1. Melting Point

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Measured
Remarks:	

Results

Melting point value:	360 °C
Remarks:	

References NPIRI, 2000

Other

Data is consistent with melting points for the class of pigments and other available measurements

A2. Melting Point

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Method:	Measured
Remarks:	2002

Results

Melting point value:	350 °C
Remarks:	Decomposition is reported at 200 °C

References

IUCLID Database
reliable with restrictions

Other

Data is consistent with melting points for the class of pigments and other available measurements.

B. Boiling Point

Test Substance

Test substance:	SOLID
Remarks:	

Method

Method:	
Remarks:	

Results

Boiling point value:	
Remarks:	

References

Other

C1. Vapor Pressure

Test Substance

Test substance:	C.I. Pigment Yellow 14 (CAS NO.: 5468757) Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Estimation
Remarks:	

Results

Vapor pressure value:	2.4E-23 Pa
Temperature:	
Remarks:	

References

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

C2. Vapor Pressure

Test Substance

Test substance: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Remarks:

Method

Method: Estimation Modified Grain Method

Remarks:

Results

Vapor pressure value: 2.05 E-022 mm Hg

Temperature: 25 °C

Remarks:

References MPBPWIN v. 1.41, Syracuse Research Corporation, Syracuse, New York

Other

D. Partition Coefficient

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	Octanol-water
Remarks:	

Results

Value:	8.1.mg/l
Remarks:	Calculated 2002 (EPI WIN 3.1)

References

Log Kow partition coefficient cannot be meaningfully determined for this compound and its structural surrogates, solubility in water and octanol are too low to produce a meaningful value.

Other

E. Water Solubility

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	About 5 mg of the pigment is dispersed in 30 ml of water and shaken for a period of seven hours at a controlled temperature of 80 °C, followed by a second, third and fourth period at 25 °C (16,40 and 64 hours) to approach the equilibrium between the pigment in solution and the solid. The clear solution is measured spectrophotometrically.
Remarks:	Measured Value

Results

Value:	<.02 mg/L
Temperature:	25 °C
Description:	Very Low Solubility
Remarks:	

References

Az, R., Investigations into the solubility of selected generic organic pigments in water and n-octanol, Clariant, unpublished results, July 5, 2001.

Other

The author stated that the very low solubility of pigment in water or octanol did not allow for any absorbance measurement.

Environmental Fate Endpoints

A. Photodegradation

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Estimate
Test type:	Water\sunlight
Remarks:	

Results

Temperature:	
Degradation Rate	
: Half-life	
Ozone reaction:	3.7 ?? Hours, No ozone reaction estimation
Remarks:	

Conclusions

References

AOPWIN v. 1.91, Syracuse Research Corporation, Syracuse, New York

Other

B. Stability in Water

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	estimate
Test type:	
GLP:	
Remarks:	

Results

Half-life:	
Percent hydrolyzed in 5 days (120 hs) at 50 °C :	
Remarks:	Hydrolysis rate is extremely slow. Under the conditions of an anaerobic biodegradation test with a similar compound (biazoaryl pigment), no hydrolysis within 56 days.

Conclusions

Data Quality

Remarks:

References HYDROWIN v. 1.67, Syracuse Research Corporation, Syracuse, New York

Other

C. Biodegradation

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	OECD 301C
Test type:	Biological Oxygen Demand (BOD)
GLP:	Yes
Year:	1992
Remarks:	Degree of degradation after 28 days (Japanese standard activated sludge)

Results

Results:	C.I. Pigment Yellown13 is not readily biodegradable
Remarks:	

Conclusions

Data Quality

Remarks:

References

Madsen, T., Aerobic biodegradability of Pimatex Yellow 2GL- modified MITI test (I), VkI Water Quality Institute, 1995 (41). See also IUCLID DATASET C.I. Pigment Yellow 13.

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks: 4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Test type: Estimation
Model used: Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
Remarks:

Results

Model data and results:

Distribution (%)	
Air	.000162
Water	.656
Soil	53.4
Sediment	45.9

Remarks:

Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

Conclusions

References

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210.

Other

The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15(9)**, 1618-1626 and 1627-1637.

IV. Ecotoxicity

A. Acute Toxicity to Fish

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was 94.5%

Method

Method:	
Test type:	OECD 203
GLP:	Flow through
Year:	yes
Species/strain:	2002
Analytical monitoring:	Bracgydanio rerio (zebrafish)
Exposure period:	Exposure solutions, temperature, pH, dissolved oxygen
Remarks:	96-Hour A group of 7 fishes were exposed to 2 nominal concentrations(0 and 100 mg/L),

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Biological observations:	
Statistical methods:	No effect, 96 hour EC-50 exceeds the maximum solubility of the test substance
Remarks:	

Conclusions Test substance is not toxic to fish

Data Quality

Reliability:	Reliable without restrictions
Remarks:	

References A. Schnurstein, Pigment Yellow 83, standard technical grade; 96 hour acute toxicity study in zebrafish (Danio rerio)/PT02-0300, Aventis Pharma Deutschland GmbH, 2002. See also IUCLID Dataset C.I. Pigment Yellow 83, p.21/54

Other

B. Acute Toxicity to Aquatic InvertebratesTest Substance

Test substance:

Remarks:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	Purity was 98.%
Test type:	
GLP:	
Year:	Directive 92/69/EC.2
Species/strain:	Static
Analytical monitoring:	Yes
Exposure period:	2002
Remarks:	Daphnia (*Daphnia magna*) Temperature, pH and dissolved oxygen 72 Hours

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Reproduction	100 mg/L
Biological observations:	
Statistical methods:	immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
Remarks:	

20 daphnids were exposed to2 nominal concentrations (0 and 100 mg/L)

Conclusions

Data Quality

Reliability:

Remarks:

Reliable without restrictions

References

This was a well-documented OECD guideline study conducted under GLP assurances.

Other

Migchielsen, M.H.J., Acute Toxicity Study in Daphnia Magna With C.I. Pigment Yellow 12, Project No. 341303, Notox BV, 2002

B2. Chronic Toxicity to Aquatic InvertebratesTest

Substance

Test substance:

Remarks: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo

Purity was 99.7.%

Method

Method: OECD 211
Test type: Semi -Static
GLP: Yes
Year: 1999
Species/strain: Daphnia (*Daphnia magna*)
Analytical monitoring: no
Exposure period: 21 Days
Remarks:

Results

Nominal concentration:
Measured concentration:
Endpoint value:
Reproduction
Biological observations: 0 and 1 mg/L
Statistical methods: Wilcoxon Test
Remarks: immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
No. of Living offspring 126, 115 No. of Dead offspring 32, 30

Conclusions

The test was performed at concentration far above water solubility. The particulate matter may cause physical interference with the daphnids, which may influence the results of the test. This renders the results from this test less suitable for risk assessment, but it is not expected that at maximum water solubility the substance will cause any effects.

Data Quality

Reliability: Reliable without restrictions
Remarks: This was a well-documented OECD guideline study conducted under GLP assurances.

References

Hoechst Marion Roussel, C.I. pigment Yellow 13 Daphnia Magna reproduction test, report No. 99.0405, September 1999

Other

No treatment related effects were seen.

C. Toxicity to Aquatic Plants

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity 94.5%

Method

Method:	Directive 92/69/EEC
Test type:	static
GLP:	Yes
Year:	2002
Species/strain:	Selenastrum capricornutum
Endpoint basis:	
Exposure period:	72 hours
Analytical procedures:	
Remarks:	

Results

Nominal concentration:	100 mg /L
Measured concentration:	
Endpoint value:	EC_{50} (72 hour) 190mg/L
NOEC:	equal to maximum solubility
Biological observations:	
Was control response :satisfactory	Yes
Statistical Methods:	ANOVA
Remarks:	

Conclusions No statistically significant inhibition of biomass and growth rate.

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Migchielsen, M.H.J. Fresh Water Algal Growth Inhibition Test With C.I. Pigment Yellow 83, Project No. 341292, Notox BV, 2002

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5dimethoxylphenyl)-3-oxobutyramide Purity was unknown
Remarks:	

Method

	Acute lethality; Other
Method:	LD_{50} estimate
Test type:	No (Pre-GLP)
GLP:	1972
Year:	unknown
Species/strain:	Oral gavage
Route of exposure:	5,000 & 10,000 mg/kg bw
Dose levels:	
Remarks:	

Results

	LD_{50} = >10,000 mg/kg.
Value:	
Deaths at each dose:	
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

	Reliable with restrictions
Reliability:	The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.
Remarks:	

References

Thomann P., Acute Oral Lethal Dose in Rats, Exp. No. 367/35 Ciba Geigy Ltd. 1972

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was unknown

Method

Method:	Acute lethality; OECD 401
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1984
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	5,000 mg/kg administered to animals 5 male, 5 female only 35% of the test mixture was C.I. Pigment Yellow 83

Results

Value:	
Deaths at each dose:	LD_{50} = >1,750 mg/kg.
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability:	
Remarks:	Reliable with restrictions The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for these pigments and pigments of this class.

References

Rupprich, N. and Weigard, W. Colanyl-Geib HR30 Prufung der akuten oralen Toxizitat an der mannichen und weiblichen Wistar -Ratte/ 84.0243, Hoechst AG 1984

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	Purity was unknown

Method

Method:	Acute lethality; Other
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1968
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	

Results

Value:	LD_{50} = >5,000 mg/kg.
Deaths at each dose:	
Remarks:	

Conclusions Material would be considered as not toxic.

Data Quality

Reliability:	Reliable with restrictions
Remarks:	The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.

References Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

Repeated Dose Toxicity Test

Substance	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Test substance:	4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1979
Species/strain:	Rat RAI f SPF
Route of exposure:	Inhalation
Duration of test:	21 days + 21 day post exposure
Exposure levels:	54, 157, 410 mg/cubic meter air
Sex:	Male and female
Exposure period:	21 days
Post-exposure observation period:	21 days
Remarks:	

Results

NOAEL (NOEL): <54mg/m3
Mortality: none
Clinical signs: none observed
Slight decrease in body weight for males and females during exposure at 410 mg/m3.food consumption: no treatment related effects, ophthalmoscopic examination: no treatment related effects, Slight increase of ASAT in males at 410 mg/m3: Hematology: no treatment related effects, at 410 mg/m3 absolute and relative weight of lungs is increased for males and females on day 21 and increased relative lung weight after recovery period: some yellow discoloration of the lungs in all treated animals, Histopathology: in the lungs focal accumulation of small brown yellow infringement particles in the cytoplasm of the hystiocytic elements in the interstitium, in alveoli, bronchi and lymphohistiocytic infiltration in all animals at 410mg/m3, no regression of lung effects observed after recovery period.

Conclusions Test substance is not significantly toxic

Data Quality

Reliability: Reliable without restriction, This is a very well documented study.
Remarks:

References: Sachsse, K., 21 days aerosol inhalation toxicity study in rats, Project No. 785465, Ciba Geigy Ltd. (Switzerland), 1979. C.I. Pigment Yellow 13

Other

Repeated Dose Toxicity Test

Substance	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Test substance:	Commercial purity 98%
Remarks:	

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1984
Species/strain:	Rat
Route of exposure:	Gavage
Duration of test:	97 days
Exposure levels:	500 mg/kg bw
Sex:	Male and female
Exposure period:	
Post-exposure observation period:	
Remarks:	

Results

NOAEL (NOEL):	no treatment related changes

Conclusions Test substance is not significantly toxic

Data Quality

Reliability:	Reliable with restriction
Remarks:	

References: Colipa (1984) cited in BIBRA report 2nd Edition 1991

Other

C. **Genetic Toxicity - Mutation**

Test Substance

Test substances:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo
Remarks:	

Method

Method:	In Vitro Mutagenicity
Test type:	Ames
GLP:	No
Year:	Unknown
Species/strain:	Salmonella typhimurium
Metabolic activation:	Rat liver S9 Mix (Aroclor 1254-induced)
Concentration tested:	
Remarks:	

Results

Result:	Negative
Cytotoxic concentration:	
Precipitation concentration:	Negative
Genotoxic effects	Negative
With activation:	
Without activation:	
Statistical methods:	
Remarks:	

Conclusions Reliable with restrictions, This is a well documented study largely following OECD guideline 471

Data Quality

Reliability:	Hoechst AG, Study of the mutagenic potential of the compound T2015-26 with salmonella typhimurium (Ames Test) Report No. 575/81, 1981
Remarks:	

References

C. **Genetic Toxicity - Mutation**

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Remarks: 96.9% pure

Method

Method: OECD471

Test type: Ames

GLP: Yes

Year: 2002

Species/strain: Salmonella typhimurium TA98, TA100, TA100, TA102, TA1535 AND TA 1537

Metabolic activation: With and without

Concentration tested: 50, 60, 500, 1600, and 5000 ug/plate with and without activation

Remarks:

Results

Result: Negative in all bacterial strains with and without activation

Cytotoxic concentration:

Precipitation concentration:

Genotoxic effects

With activation: Negative Without activation: Negative Statistical methods:

Remarks:

Conclusions

Data Quality

Reliability: Reliable without restriction Remarks:

References Kauffmann, H.M. C.I. Pigment Yellow 83 Bacterial reverse mutation test (standard plate test) and prival modification (preincubation test) report No. PT02-0190, Aventis Pharma Deutschland GmbH, 2002, C.I. PIGMENT Yellow 83,

Other

D. Genetic Toxicity – Chromosomal Aberrations

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-
Remarks:	

Method

Method:	Chromosomal aberration test
Test type:	CHO cells
GLP:	no
Year:	
Species/strain:	Chinese Hamster CHL Cells
Exposure period:	
Remarks:	

Results

Result:	Negative
Genotoxic effects:	Negative
Concentration tested	Without S9 1.6, 5.0, 16, 50, and 160 ug/ml With S9 .5, 1.6,5.0,16 and 50 ug/ml
Statistical methods:	
Remarks:	

Conclusions Negative

Data Quality

Reliability:	
Remarks:	Reliable with restriction

References

Other Central Data Management NTP, NTP unpublished results, NTP/NIEHS Toxicology data on C.I. Pigment Yellow 12, , IUCLID Dataset p. 48 of 68

E. **Developmental Toxicity**

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	
GLP:	OECD 422 repeated dose developmental and reproductive
Year:	
Species/strain:	2001
Sex:	Wistar Rats
Route of exposure:	Male and Female
Exposure levels:	Gavage
Actual doses received:	0, 50, 200 and 1000 mg/kg bw
Exposure period:	
Duration of test:	Males 4 weeks, Females 6 to 7 weeks
Remarks:	

Results

Maternal toxicity

NOEL: No Mortality, body weight: no treatment related effects, food consumption: no treatment related effects, clinical signs: all females showed diarrhea including controls; feces discoloration was observed in all treated females; incidental animals of all dose groups showed lethargy, hunched posture, labored respiration, salivation, chromodacryorrhea, alopecia, scabs and piloerection, hematology RBC Hb/hematocrit increased at 50 mg/kg, clinical biochemistry: ALAT/ASAT increase at 1000 mg/kg; phosphate decreased and glucose increased at 200 mg/kg; creatinine decreased at 50 mg/kg, gross pathology incidence an severity; 1/10 greenish contents of the caecum at 1000 mg/kg , no treatment related organ weight changes no histopathologic treatment related effects, number of litters = 9 at all doses
Males, no treatment related effects body weight, food consumption and functional observations, clinical signs same as females above, hemotolgy: RBC increased at 50 mg/kg, Reproductive, successful mating ,no treatment related effects, 100% mated 9/10 pregnant per dose level, none aborting duration of gestation 21-22 days, Fetal data 9 litters at all dose levels,

Parental toxic responses:

Fetal toxic responses dose:	1000 mg/kg bw parental and reproductive
Statistical Methods:	
Remarks:	

Conclusions No treatment related reproductive effects were seen in the study. NOAEL 1000 mg/kg bw for parental and reproductive toxicity

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Combined Repeated Dose Toxiicty Study with Reproduction/ Developmental Toxicity Screening Test with C.I. Pigment Yellow 12 Administered by Oral

Other Gavage in Wistar Rats May 3, 2001, C.I. Pigment Yellow 12 p. 59 of 68

F. Toxicity to Reproduction

Test Substance See Above

Test substance:

Remarks:

Method

Method:
GLP:
Year:
Species/strain:
Sex:
Route of exposure:
Exposure levels:

Exposure period:

Duration of test:
Remarks:

Results

Maternal toxicity NOEL:
Parental toxic responses:
Fetal toxic responses dose:
Statistical Methods:
Remarks:

Conclusions

Data Quality

Reliability:
Remarks:

References

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	

Method

Method:	Irritation to the rabbit eye
Test type:	eye irritation
GLP:	yes
Year:	1996
Species/strain:	rabbit, New Zealand albino (chbb:Nzw)
Route of exposure:	
Dose levels:	
Remarks:	

Results

Value:	cornea .55, iris .33 conjunctive (redness) 2.44) (Chemosis .88)
Deaths at each dose:	
Remarks:	observation times 1,24,48,72 hours, 7 days at 24 and 72 hours and 7 days with fluorescein Reversibility within 14 days

Conclusions Slightly irritating

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Eye Irritation in the Rabbit/96.0887, Hoechst AG,1996, C.I. Pigment Yellow 83

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	purity 79.1 %

Method

Method:	Skin irritation to the rabbit
Test type:	Skin irritation SEMIOCCLUSIVE
GLP:	yes
Year:	1996
Species/strain:	rabbit New Zealand albino
Route of exposure:	
Dose levels:	500 mg Vehicle, polyethylene glycol 400
Remarks:	

Results

Value:	slightly irritating reversibility - 7 days
Deaths at each dose:	
Remarks:	

Conclusions

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Dermal Irritation in the Rabbit / 96.0853, Hoechst AG, 1996, C.I. Pigment Yellow 83

Other

Chronic Dose Toxicity Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Method

Method: Chronic Toxicity
Test type: Repeated oral dose
GLP: unknown
Year: 1978
Species/strain: Sprague-Dawley Rat
Route of exposure: Oral gavage
Duration of test: 104 Weeks
Exposure levels: 0, .1, .3 and .9 %
Sex: Male and Female
Exposure period:
Post-exposure observation period:
Remarks:

Results

NOAEL (NOEL): NOAEL for Rats 630 mg/kg bw, No treatment related effects, body weight, clinical signs, food consumption, necropsy and histopathology
urine analysis (no dichlorobenzidine in urine (<LOD .3 ug/ml)

No cancerous response. No toxicity or mortality as a result of exposure

Conclusions

Data Quality

Reliability: valid with restriction
Remarks:

References

Leuschner, F., Carcinogenicity Studies of Different Diarylide Yellow Pigments in Mice and Rats, Toxocol. Lett. 2, 253-260, (1978), C.I. Pigment Yellow 83.
See also, Longstaff, E., An Assessment and Categorization of the Animal Carcinogenicity Data on Selelcted Dyestuffs and an Extrapolation of Those Data to an Evaluation of the Relative Carcinogenic Risk to Man, Dyes and Pigments 4, 243-304, 1983. See also Decad, G. M. et al. Fate of Water - Insoluble and Water Soluble Dichlorobenzidine - Based Pigments in Fischer 344 Rats, Journal of Toxicology and Environmental Health, Vol. 11, pp. 455-465, 1983. (Radio labeled labeled study of C.I. Pigment Yellow 12 indicating no detectable pigment in any tissue at points up to one day.)

Other